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of these documents is pivotal in that none provides the sole or principal basis for the Agency's conclusion that cigarettes and smokeless tobacco are intended to affect the structure and function of the body under the Act. Further, as discussed below, the decision to keep these materials confidential did not undermine the quality of the public participation in the Agency's jurisdictional determination. In sum, the procedures the Agency followed in assembling a public record in support of this jurisdictional determination are not analogous to the facts described in cases like *Portland Cement Ass'n*, *Nova Scotia Food Products*, and *United States Lines*.

**2. The Agency's Use of Confidential Documents**

**a. Confidential Documents on Which the Agency Did *Not* Rely**

The Agency placed in a confidential docket 75 documents from the approximately 210,000 pages of materials the Agency made available at the opening of the jurisdictional determination and the companion rulemaking proceeding. The Agency identified each of these 75 documents for the public in an index filed on September 29, 1995, on the public docket. *See* 60 FR 66981, 66982 (Dec. 27, 1995). Of these 75 documents, 73 were not even relied upon by the Agency to support either the Proposed Rule or the Jurisdictional Analysis.

Sixty-one of these 73 confidential documents consisted either of commercial information and trade secrets which the industry urged FDA to keep confidential (Confidential Documents 1-12, 16-21, 62-73), or unpublished manuscripts for which the Agency lacked the authors' permission, as of September 29, 1995, to publicly release

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28 Ref. 463-2). The Kiefer document appeared on the public docket with certain trade secret and confidential information redacted from the document. The Curran document was made available to the public in full.

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(Confidential Documents 22-52). The remaining twelve documents were either proprietary reports and other copyrighted information—such as financial reports generated by Dun and Bradstreet—which the Agency lacked permission to reprint (Confidential Documents 13-15, 53-58), or confidential documents that support a pending new drug application (Confidential Documents 59-61).

Again, the Agency did not rely on any of these 73 documents as support for the Jurisdictional Analysis. Therefore, the Agency was not even required to include these documents in the administrative record. *See* 21 CFR 10.40(b)(vii). It likewise follows that because the Agency did not rely upon these documents, the decision to protect them cannot be said to have unfairly interfered with the public's ability to question the Agency's Jurisdictional Analysis. *See Mid-Tex Electric Cooperative, Inc. v. Federal Energy Regulatory Commission*, 773 F.2d 327, 344 (D.C. Cir. 1985) (agency's failure to disclose two studies was "manifestly harmless" because the agency did not rely on the studies to support any finding or conclusion); *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (there is no violation of the APA's notice requirements where the agency has declined to disclose materials on which it did not rely in proposing the rule); *B. F. Goodrich Co. v. Dept. of Transportation*, 541 F.2d 1178, 1184 (6th Cir.) (only the basic data "upon which the agency relied in formulating the regulation" must be published for public comment), *cert. denied*, 430 U.S. 930 (1976); K. Davis, *Administrative Law Treatise*, § 7.3 at 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators"). The fact that the Agency went well beyond existing requirements to

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make publicly available thousands of additional documents for public review—in recognition of the uniqueness and public importance of this proceeding—should not be used now as a basis for suggesting that the Agency was under a legal obligation to disclose publicly all information that it had at hand.

Finally, at the close of this jurisdictional determination and the companion rulemaking proceeding, the Agency will supplement the public docket with copies of those confidential items for which the Agency previously lacked permission to publish, but for which permission has now been granted. Most of the unpublished manuscripts in the confidential docket—none of which were relied upon by the Agency to support last year's Jurisdictional Analysis—will be available through this addition to the public record.

**b. Confidential Information on Which the Agency Relied**

In support of the Jurisdictional Analysis, FDA relied on only 2 of the 75 documents designated as confidential: a summary of notes taken by FDA investigators during site visits to manufacturing plants run by Brown & Williamson, Philip Morris, and R. J. Reynolds (Confidential Document 74); and a 1991 Brown & Williamson handbook on leaf blending and product development (Confidential Document 75).<sup>1232</sup> The Agency described the two confidential documents cited in the Jurisdictional Analysis in an index made available to the public on September 29, 1995. In addition, the Agency relied on

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<sup>1232</sup> The Agency did not attribute ownership of the handbook in the Jurisdictional Analysis, or in the September 29, 1995, index to the administrative record. However, in a set of comments filed by Brown & Williamson, the company itself acknowledged publicly its ownership of the handbook. Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 37-38. See AR (Vol. 529 Ref. 104).

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two lines of text that it redacted from a document regarding cigarette filters that the Agency placed on the public docket.<sup>1233</sup>

The Agency placed in the confidential docket the summary of notes at the request of Brown & Williamson, Philip Morris, and R. J. Reynolds, each of whom urged the Agency to keep confidential their commercial information and trade secrets. *See* 60 FR 66981 (Dec. 27, 1995). Brown & Williamson likewise vigorously urged the Agency not to put its leaf blending handbook on the public docket.<sup>1234</sup> These same companies have now commented that it was improper for the Agency to rely on this information because the information “cannot be subjected to comment by interested parties.”<sup>1235</sup>

The Agency disagrees that its decision to place in the confidential docket these two documents (out of 20,000 pages of documents the Agency cited in support of its position), or rely on two lines of redacted text from a document the Agency made available to the public, in any way undermined the public’s ability to comment on the Agency’s Jurisdictional Analysis. Nor does the Agency agree that its reliance in this proceeding on confidential commercial information or confidential industry trade secrets violated the APA.

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<sup>1233</sup> *See* Kiefer JE, Tennessee Eastman Company, *Cigarette Filters for Altering the Nicotine Content of Smoke* (Report No. 71 5003 7), Aug. 18, 1971, at 1-2. *See* AR (Vol. 28 Ref. 463-1). Although the Agency also redacted from the document the confidential measurements of the effects of filter additives on nicotine content in cigarettes smoke, the Agency did not directly rely on these measurements in the text of the Jurisdictional Analysis.

<sup>1234</sup> Letter from Krulwich AS (counsel to Brown & Williamson) to Porter MJ (FDA) (Jan. 11, 1996). *See* AR (Vol. 711 Ref. 38).

<sup>1235</sup> Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 14. *See* AR (Vol. 535 Ref. 96).

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First, none of the authorities cited in the comments supports the proposition that agencies, even in a rulemaking context, are precluded from considering or relying upon privileged documents. To the contrary, several courts have indicated that reliance on protected documents in an informal rulemaking proceeding is permissible. *See Home Box Office, Inc. v. Federal Communications Commission*, 567 F.2d 9, 58 n.130 (D.C. Cir.) (stating, in *dicta*, that “it is conceivable that trade secrets . . . if proffered as the basis for rulemaking, should be kept secret. *Cf.* 5 U.S.C. 552.”), *cert. denied*, 434 U.S. 829 (1977); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 251 (2d Cir. 1977) (“We can think of no sound reasons for secrecy or reluctance to expose to public view (*with an exception for trade secrets or national security*) the ingredients of the deliberative process” (emphasis added)).

Second, the Agency put the confidential materials on which it relied in sufficient context so that the public could comment on, and challenge, the Agency’s use of the material. With respect to the handbook, the Agency quoted from the document in several instances in the Jurisdictional Analysis. *See* 60 FR 41453, 41710–41711; 60 FR 41453, 41510–41511. The Jurisdictional Analysis also incorporated testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on June 21, 1994, in which the Commissioner discussed the content of the handbook and quoted from relevant portions. *See* 60 FR 41453, 41710–41711 and nn. 443-447. In both settings, the Agency made the language from the handbook on which the Agency relied available, and carefully explained how these portions of the handbook were relevant to the overall proceeding. Thus, while the Agency kept the bulk of the document confidential, it provided as much actual content and context as possible to allow

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for meaningful public comment on the quoted passages. In the end, the only comments the Agency received regarding the decision to keep the handbook confidential were from tobacco industry trade associations with whom Brown & Williamson jointly submitted comments. No other commenter objected to the Agency's reliance on the handbook or the way the Agency safeguarded information the industry regarded as confidential.

As for the summary of notes (Confidential Document 74), the Agency assembled this document from handwritten notes recorded by FDA employees during site visits in March, April, and May 1994 to Brown & Williamson, Philip Morris, and R. J. Reynolds, as well as handouts distributed by R. J. Reynolds and Philip Morris during those visits. During these visits, company representatives requested that FDA employees not disclose certain confidential commercial and trade secret information. The Agency, in an effort to accommodate this request, withheld from the public docket trade secret or confidential commercial information provided to the Agency.

As with the handbook, the Agency is not persuaded that the public has been prejudiced by the decision to withhold this comparatively small amount of information. Again, the Agency presented the notes in context to allow the public to see precisely what points they were being used to support. *See* 60 FR 411453, 41704–41719. The Agency also put on the public docket the original handwritten notes from these visits (less the redactions needed to protect information the companies regarded as confidential), so that the public could see as much of what transpired as possible and understand the full context of the protected information. As with the handbook, nonindustry commenters did not object to this procedure.

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Finally, with respect to the Tennessee Eastman document, the Agency placed the document on the public docket, but redacted the two lines of text that identified the name of a manufacturer who used polyethylene glycol in cigarette filters, resulting in a higher nicotine delivery than from other cigarettes. The text that identified the name of the manufacturer (both as it appeared in the Jurisdictional Analysis and in the Tennessee Eastman document), was redacted from public view to protect that firm's confidential commercial information and its trade secrets. The balance of the text of the Tennessee Eastman document, as well as the balance of the text of the Jurisdictional Analysis, gave the public ample opportunity to comment on the Agency's findings regarding "the use of filter additives to enhance nicotine delivery." 60 FR 41453, 41715.

In sum, the Agency carefully developed a mechanism to accommodate the industry's need to protect its confidential commercial information and its trade secrets, while at the same time providing ample notice to the public of the information on which it relied in this proceeding. Based on the quality and quantity of comments received, and based on the lack of objection from other commenters, the Agency is not persuaded that its decision to rely on confidential information prejudiced the public's ability to participate in the Agency's jurisdictional determination. Rather, the lack of comment from the public at large confirms that the Agency struck a reasonable balance between the need for public process, the need to protect trade secrets and confidential commercial information, and, of course, the need to protect the public health.

### 3. The Claim that FDA Relied on “Unknown” Undisclosed Data

A tobacco industry comment claimed that the Agency withheld certain data and calculations used to construct a series of charts showing that nicotine and tar levels in smoke have risen steadily from 1982 to 1991. *See* 60 FR 41728–41731.

As the comment acknowledges, the Agency relied on summaries of industry-supplied data gathered by the FTC to construct these charts. *See* 60 FR 41727–41731. The comment claims, however, that the Agency relied on “unknown” data to construct the tar and nicotine yields for the years 1982 and 1984–86.<sup>1236</sup> According to the comment, the FTC did not generate data for these years. The industry comment also questions where the Agency obtained the sales figures used to calculate weighted averages, how the Agency calculated these averages, and why the Agency’s figures did not always track those of the FTC.

The industry raised precisely the same issues in a December 8, 1995, letter to the Agency. In a December 27, 1995, response, FDA identified the specific documents in the administrative record that address each concern.<sup>1237</sup>

The only issue not fully resolved by that exchange of correspondence is the industry’s claim that FDA’s figures for 1990 and 1991 reflect fewer brands than FTC reported on for those years. As the Agency stated in its December 27 letter, it is not apparent from the face of the charts what, exactly, the industry association is referring to.

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<sup>1236</sup> Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 3. *See* AR (Vol. 535 Ref. 96).

<sup>1237</sup> *See* Letter from Schultz WB (FDA) to Merrill R (Covington and Burling) (Dec. 27, 1995). *See* AR (Vol. 711 Ref. 7).

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Although the association acknowledges this exchange of correspondence in its January 2, 1996, comments, it failed to provide any greater specificity in its comments than it did in the December 8 letter.

FDA based its charts on sales-weighted averages calculated by the FTC based on industry-supplied data. In most years, the FTC publishes this data in two reports: one on sales volume and one on tar, nicotine, and carbon monoxide content. Some manufacturers, however, fail from time to time to report to the FTC for each brand on all three of the values of interest to FDA, namely, tar, nicotine, and sales volume. The FTC, therefore, excluded from the sales-weighted averages it supplied to FDA any brand for which the manufacturer failed to supply data on any of the three values of interest to FDA. That is why, in 1990 and 1991, the points FDA plotted on its graphs reflect fewer brands than the total number of brands that the FTC reported on in those years. *See* section II.C.6.c.ii., above.

The decision to exclude in 1990 and 1991 brands for which FTC lacked complete data was reasonable. The slight variation between FDA's figures and FTC's figures for 1990 and 1991 are not the result of FDA having relied on "unknown" or "undisclosed" data. Rather, FDA has made publicly available all of the information necessary to allow for meaningful comment on these charts.

**4. The Claim That FDA Failed To Include in the Record NDA Data on Which It Relied**

One comment claimed that the Agency relied on studies in seven new drug applications (NDA's) for the proposition that a high proportion of smokers are addicted to nicotine, but failed to make adequate disclosure of these NDA's. In particular, this

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comment stated that the Agency failed to include any information in the public docket for NDA 18-612 (Nicorette gum, 2 mg) and NDA 20-385 (Nicotine nasal spray), and included only summaries for five other NDA's the Agency cited. As discussed below, FDA did in fact include in the public docket sufficient information regarding the NDA's on which it relied. As for the particular NDA studies the Agency referenced, the relevant data in support of these studies was recounted in sufficient detail in Appendix 1 to the Jurisdictional Analysis to provide the public a meaningful opportunity to comment.

**a. The Agency's Reference to Five NDA's**

With respect to NDA 18-612 (Nicorette gum, 2 mg), the Agency did not rely on the NDA for this product in either the Proposed Rule or the Jurisdictional Analysis. *See* 60 FR 41549, n.62 (citing only to NDA 20-076 Habitrol, NDA 20-150 Nicotrol, NDA 19-983 ProStep, NDA 20-165 Nicoderm, NDA 20-066 Nicorette, 4 mg); *see also* 60 FR 41550, n.64 (citing only to the same five NDA's listed in footnote 62 of the Jurisdictional Analysis). Therefore, the Agency is under no obligation to include in the public record the NDA itself or a summary of the application.

With respect to NDA 20-385 (Nicotine nasal spray), the Agency similarly did not rely on the NDA for this product in either the Jurisdictional Analysis or the proposed rule. *See* 60 FR 41549, n.62 and 60 FR 41550, n.64. While the Agency did discuss an aqueous nicotine nasal spray in the Jurisdictional Analysis, the Agency did not rely on the NDA itself to support its point. Rather, the Agency relied on the discussion of the nasal spray at an August 1994 FDA Drug Abuse Advisory Committee meeting. The relevant portions of the transcript, cited in footnote 116 in the Jurisdictional Analysis, and the background materials provided to the advisory committee, cited in footnote 117, were included in the